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In The

Supreme Court of the United States

October Term, 1948

No. 134

Research Laboratories, Inc.,
Petitioner,

v.

United States of America

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITIONER'S REPLY BRIEF

Argument

I.

In its brief in opposition to certiorari, respondent first contends (pp. 8-15) that the principle of *School of Magnetic Healing* v. *McAnnulty*, 187 U. S. 94, and related cases, has been limited by subsequent developments in medical science. Respondent's argument seems to run as follows: The *McAnnulty* rule must be limited to cases where efficacy is a matter of opinion, and not subject to factual proof. Evidence as to actual use, clinical observations, and the value of individual ingredients is factual data, not matter of opinion. Such evidence is available now whereas it was not at the time of the *McAnnulty* decision. Whenever the Gov-

ernment introduces that type of evidence, it is proper to submit the case to the jury, no matter what the nature of the evidence in support of the product, for then the question has become one of fact rather than one of opinion.

There are a number of answers to this contention:

(1) In the case at bar, no matter how respondent may attempt to characterize its evidence, the fact remains that its witnesses were asked for and gave only their *opinions* as to effectiveness (R. 225-226, 271-272, 276, 356-359, 404, 488, 560-562, 580-581). The Court of Appeals time and again referred to respondent's evidence as *opinion* testimony (R. 1111, 1112, 1114, 1115, 1116, 1117, 1118). The true fact is that respondent's witnesses testified as to their *opinions*, those opinions being based on actual use or information concerning ingredients.

(2) Petitioner introduced precisely the same kind of evidence in support of the product. Five eminently qualified physicians, all of whom had actually used the product for a number of years and three of whom had conducted extensive clinical tests with it, testified that it was effective (see summary of evidence at pp. 3-4 of Petition).*

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*In an effort to deprecate the weight of petitioner's testimony, respondent refers to the fact that some of it related to Sal-Trag, a concentrated form of Nue-Ovo, and states that it was "admitted" that Sal-Trag contains two ingredients not present in Nue-Ovo (Resp. Br. 6, n. 2). That statement apparently is inadvertent. In respondent's cross-examination of petitioner's witnesses, two vague references to a possible difference in ingredients were made (R. 792, 803). In both instances, the testimony was plainly inadmissible and inconclusive. And in each case a reading of the entire testimony of the witness demonstrates beyond doubt that he testified that the two products are the same. The uncontradicted evidence is that the products are identical, and both courts below were satisfied in that regard (see Petition 3, n. 2). In any event, the question here is not the weight of the evidence before the jury on the issue of effectiveness. The question is whether it was improper to submit that issue to the jury at all, since there was respectable medical opinion in support of the product. Furthermore, since the verdicts here were general and it cannot be determined on what theory the jury rested its decision, the propriety of permitting the jury to decide the question of effectiveness must be tested on the assumption that the jury found the products to be the same. *Williams* v. *North Carolina*, 317 U. S. 287, 291-292; and see discussion and cases cited at p. 7, *infra*.

(3) The type of evidence introduced by respondent is not the result of any scientific development since the *McAnnulty* decision. Respondent apparently draws the line between testimony based on actual experience with the product, and testimony based simply on knowledge of ingredients without actual experience. Respondent calls the former "factual data" and the latter "matter of opinion." But certainly doctors have always been able to testify from experience with a product. We agree that such testimony is better founded. Nevertheless, it is still opinion evidence, and there may be a wide divergence of opinion based on the same kind of experience, as there was in this case. In *United States* v. *Fifty-nine Tubes, More or Less, etc.*, 32 F. Supp. 958, 962 (S. D. N. Y.), the court held, in conflict with the decision below, that evidence based on laboratory experiments and clinical tests was opinion evidence and subject to the rule on difference of expert opinion.

(4) The decision below would not only limit the *McAnnulty* principle, as both the lower court (R. 1107, 1110) and respondent (Resp. Br. 11) admit, but it would completely nullify that principle. Whenever there is any difference of medical opinion concerning a product's effectiveness, the Government can secure this type of "factual data" based on actual use of the product. Under the decision below, the question of effectiveness would then go to the jury, no matter how much evidence there might be in favor of the product based on the same type of actual experience. Apparently respondent believes that the jury's qualifications to resolve the conflict between doctors improve if the doctors have had more experience with the product.

(5) Contrary to respondent's suggestion (Resp. Br. 12-15), there is nothing in *Seven Cases* v. *United States*, 239 U. S. 510, which even remotely supports such a result. In *McAnnulty*, and later in *United States* v. *Johnson*, 221 U. S. 488, the Court indicated that there probably would be a

difference of opinion concerning the efficacy of substantially all medical products or treatments, and therefore to avoid serious questions of constitutionality on grounds of uncertainty federal statutes should be construed not to apply to any such case. In *Seven Cases*, the Court recognized that there could be assertions as to efficacy which "are in no sense honest expressions of opinion but constitute absolute falsehoods and in the nature of the case can be deemed to have been made only with fraudulent purpose", and that Congress could properly prohibit such statements (239 U. S. at 518). But the Court carefully pointed out that "Congress deliberately excluded the field where there are honest differences of opinion between schools and practitioners" (239 U. S. at 517). Thus that decision simply means that Congress can proscribe statements concerning efficacy where there is no respectable medical opinion in support of the product. It in no way suggests that, where there is an honest difference of medical opinion, the case may be permitted to go to the jury for its conclusive determination even if the Government produces any evidence based on use of the product.

(6) Finally, even if it be assumed that there is rational basis for limiting or nullifying the doctrine of the *McAnnulty* and related decisions, we submit that it should not be done without review by this Court.

(7) As an adjunct of its argument concerning the *McAnnulty* rule, respondent suggests that Congress intended section 502(a) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 352(a)) to change the rule so as to permit submission of the issue of effectiveness to the jury where there is evidence based on use of the product (Resp. Br. 11). In support of this view, respondent points to the House Report on the bill which became the present Act (Resp. Br. App. 18-20). But that Report proves just the contrary. It demonstrates that Congress considered that representations concerning curative effects fall into three

categories under the present law. *First,* where there is no qualified medical opinion in support of the representation, it is prohibited. *Second,* if only a few experts regard the representation as true but the great body of experts consider it untrue, the representation is prohibited under section 201(n) (21 U. S. C. 321(n)) unless it is qualified by a statement showing the existence of conflicting opinion (see the legislative history at note 6 on page 9 of the Petition). *Third,* where there is an honest difference of qualified medical opinion, the representation is not prohibited and the case may not be submitted to the jury to resolve the conflict of opinion. The House Report in no way suggests that a case involving conflicting opinions is to go to the jury if the Government introduces evidence concerning actual experience with the product.

Moreover, the desire of Congress is manifest in more than the House Report. Congress examined into the question repeatedly and rejected proposals to the contrary. The Tugwell Bill proposed that a drug be misbranded "if its labeling bears any representations * * * contrary to the *general agreement* of medical opinion" (S. 1944, 73d Congress, emphasis supplied; see also 79 Cong. Rec. 4749, 5024, and 5223). S. 2800 of the 73d Congress proposed to define misrepresentation as any statement "not supported by substantial medical opinion or by demonstrable scientific facts." S. 5 of the 74th Congress was much the same, but even then the committee report stated (Senate Report No. 646, 74th Congress):

> There exist now, and perhaps always will exist, differences of medical opinion with respect to the effect of therapeutic agents. Any attempt to regulate by law in those fields where honest differences of opinion exist between groups of qualified persons is contrary to public interest.

The House Report on this bill also explained this language as inapplicable to a representation "supported by any

sound evidence" (House Report No. 2755, 75th Congress). In the next Congress the language was revised to prohibit only a representation "not supported by persons who, by reason of scientific training and experience, are qualified as experts on the subject" and the Senate committee report thereon states (Senate Report No. 152, 75th Congress):

> The requirement that claims for drug products should be supported by medical opinion was deleted. Great difficulty always has been found in defining "medical opinion". * * * It would often be impossible to determine what the state of medical opinion is on controverted subjects.

S. 1077 of the 75th Congress was revised to provide expressly for disclosure in labeling of differences in opinion (see House Report No. 1613, 75th Congress), but in conference even this form of provision was dropped (House Report No. 1774, 75th Congress). Congress then adopted the present provision and explained it as set forth at note 6 on page 9 of the Petition here.

Again it is clear that, in any event, this Court should decide this new and important question concerning the application of the present Act.

II.

Respondent finally argues that, even if the evidence does show an honest difference of medical opinion and it was error to submit the question of effectiveness to the jury, the jury's verdict was justified under section 201(n) because the labeling did not disclose the existence of conflicting opinion (Resp. Br. 15-17). There are likewise several conclusive answers to this contention.

(1) In the first place, the record plainly shows that the case was tried and the jury's verdicts based solely on the issue of effectiveness, and not on the question of failure to disclose difference in opinion. The libels raised only the

issue of effectiveness (R. 4, 58, 80, 94), as respondent admits in its brief (p. 4). The pre-trial order stated this to be the issue (R. 22-23), as respondent likewise admits (Resp. Br. 4). The trial court charged the jury time and again that this was the only issue (see particularly R. 1090; see also R. 1057, 1060-1062, 1064-1065, 1067-1070, 1086, 1089). Petitioner's request for permission to relabel under 21 U. S. C. 334(d), which would clearly have been proper had the verdicts been based on failure to reveal conflicting opinion, was denied by the trial court on the express ground that "the jury had made a determination of the . . . ineffectiveness of this product" (R. 1096-1097). And the Circuit Court of Appeals affirmed that ruling on precisely the same ground (R. 1133-1134). In the face of all this, respondent points (Resp. Br. 16) to two sentences, taken from the context of a lengthy charge, in which the court referred broadly to section 201(n) without in any way relating that section to the question of failure to disclose difference of opinion.

(2) Even if it be assumed that the charge permitted the jury to find for respondent on alternative theories, the case must still be reversed for error in submitting the question of effectiveness to the jury. It is settled beyond question that, in the case of a general verdict after a charge involving alternative theories, the charge must be correct on each theory since it cannot be determined on which theory the jury rested its decision. *Stromberg* v. *California,* 283 U. S. 359, 368; *Williams* v. *North Carolina,* 317 U. S. 287, 291-292; *Cramer* v. *United States,* 325 U. S. 1, 36, n. 45; *Haupt* v. *United States,* 330 U. S. 631, 641, n. 1.

(3) In fact, respondent's contention in this respect argues more pointedly than anything we can say for both review and reversal in this case. Certainly the decision below cannot be sustained on both of the alternative theories, as it must be if respondent's interpretation of the charge is correct. If it be assumed that the jury's verdict was based

on a finding of ineffectiveness, the judgment was erroneous because it was improper to submit that question to the jury. If it be assumed that the jury's verdict rested on failure to disclose difference of medical opinion, the judgment was wrong in denying release of the product under bond for relabeling to comply with the law, as authorized by 21 U. S. C. 334(d). Any such defect could easily have been corrected simply by adding to the labeling a statement concerning the difference in expert opinion. Both courts below, however, denied petitioner's request in that respect on the ground that the jury had found the product to be ineffective (R. 1096-1097, 1133-1134).

Conclusion

For the foregoing reasons and those stated in the petition, it is respectfully submitted that the petition for a writ of certiorari to the United States Court of Appeals for the Ninth Circuit should be granted. The case is of importance in the administration of federal laws because, if difference of legitimate medical opinion may be treated as it was in the courts below, the reach of federal statutes relating to drugs, fair trade advertising, and the mails will be extended into a scientific field heretofore left free for professional development save in instances of real fraud. Particularly in view of the position expressed by Congress, such a change should certainly not be made except after consideration by this Court.

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